

Molecular Genetics Laboratory

Bert Vogelstein, Kenneth W. Kinzler, Directors

Dr. Bert Vogelstein

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12 June 2007

Steve Phurrough, MD MPA
Centers for Medicare and Medicaid Services
CMS
OCSQ-CAG
7500 Security Blvd
MS-C10906
Baltimore, Maryland 21244

Dear Dr. Phurrough:

This letter is a formal request to CMS for a national coverage decision on:

Colorectal cancer screening through the identification of specific colorectal cancer associated DNA mutations and alterations by the analysis of human DNA isolated from stool

In accordance with the NCD request process published in the Federal Register, September 26, 2003 (FR Vol. 68, number 187, pages 55634-55641), we request that CMS uses the collaborative NCD development track, track one (FR Vol. 68, number 187, pg 55638, IV E).

Dr. Barry M. Berger, Vice President for Laboratory Medicine, EXACT Sciences Corporation, is the primary requestor and contact for this NCD request and may be reached at any time for additional information or clarification: 508-683-1250 Ph Office, 617-293-7738 Ph Cell, email: bberger@exactsciences.com.

Sincerely,

Bert Vogelstein

Clayton Professor of Oncology & Pathology

A Comprehensive Cancer Designated by the National Concret Institute of the Cancer Institute of the Can